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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,817	11/08/2000	Jose Remacle	VANM160.001A	2892

20995 7590 11/27/2006

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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary	Application No.	Applicant(s)	
	09/582,817	REMACLE, JOSE	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,32-34,40,41,45,49 and 51-64* is/are pending in the application.

4a) Of the above claim(s) *32,33,49 and 51-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,34,40,41,45 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 30, 34, 40, 41, 45, and 64 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co.,*

Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary,

The quantity of experimentation is great, on the order of several man-years with little if any reasonable expectation of success.

The amount of direction or guidance presented,

The amount of guidance provided is extremely limited, and then the guidance is not directed to performing the method as now claimed. Page 10 of the specification states that in reading the data stored in the disc surface, "[t]he depth of the pit is engineered to be ¼ of the wavelength of the laser light." As seen above, the capture, and target molecules are bound to one another, and to the side of the disc in just such a place.

The presence or absence of working examples,

The specification has been found to comprise five examples. Upon review of the examples, it is noted that Example 1, page 28, states, "a picture was taken of this CD." Clearly, the aspect of taking a picture of this CD does not teach the method steps, reaction conditions, or claimed method steps of the now claimed invention.

Example 2 teaches the "detection of DNA on a CD with laser detection." As seen therein, the CD was:

a. first coated with a capture probe,

b. a biotinylated DNA hybridized to said capture probe

c. streptavidin-gold reacted with the hybridization complex

d. Silver Enhancement was conducted "in order to have silver precipitate where positive hybridization occurred," and

e. "This CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the information written on the CD and to read the interference due to silver precipitate."

The method of claim 30 does not recite the limitations of steps b) through e). Further, the specification, which teaches explicitly that the pits are engineered to have a depth of ¼ wavelength of the laser, is silent as to how these same pits are to be read when they comprise multiple layers of material, as well as overlays of gold. And as seen in Example 4, the assay may well comprise precipitate that is 1 μm in diameter, over which gold may be plated. While the claims and Example 2 teach that the disc may contain information as to how the disc reader may interpret the information, the specification is essentially silent as to how artifacts, variances in particle/precipitate size, or noble metal over layering is to be taken into account.

Example 5, page 23, "detection of DNA or protein on CD," in its three sentences, indicates that DNA and proteins are detected by use of a magnetic field, a limitation of claim 34. The specification is silent as to how one is to use the light beam in claim 30 to detect and/or quantify any target molecule present in the sample.

As a result of various amendments to claim 30, said claim now recites that the disc is read by a device that comprises "the two different reading devices." Clearly, the aspect of having "an apparatus comprising the two different reading devices" is critical to enabling the claimed invention. The specification, however, is essentially silent as to how such a device is to be made and used. Of the five examples provided, none of the examples actually teach using a device in accordance with the now claimed method. Example 2 is the most relevant to the claimed invention, and then it does not state that the disc was actually read, much less that it provided any useful information. And it certainly does not teach that the disc was read by a device that comprised "the two different reading devices." In Example 4, a disc was apparently read, but then, the reader used was only a single reader, not the required combined reading device. While the specification teaches that "[t]he presence of pits was found by reflection of the laser beam," such teachings do not address how one would be able to differentiate between actual test signals and false positives. And like Example 2, the specification does not teach using a device that comprises both reading devices, much less reading binary data and test results.

<u>The nature of the invention,</u>

The invention relates to conducting binding assays on or in a CD or DVD wherein the same disc comprises binary information. Two reader devices are employed. One is sued to read the assay and a second reader is used to read binary information stored in land and pits on the disc. Further, the claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The state of the prior art,

The prior art is limited, and as found in the instant disclosure, no example is provided where any target molecule or combination of molecules have been accurately and reproducibly detected by using any of the recited discs and where a two headed reader has been employed.

The predictability or unpredictability of the art, and

The predictability in the art is low. Further, the specification teaches that the discs used in the binding assay were coated with gold. It stands to reason that the coating of the disc with the noble metal would also coat the same lands and pits that comprise the requisite binary data that must be read by one of the two readers, yet the specification is silent as to how such a feat is accomplished.

The breadth of the claims.

The claimed method fairly encompasses the detection and/or quantification of any imaginable target molecule, be it of biological origin or not. The level of sensitivity and accuracy is without limit, yet the specification has not presented even a prophetic example where any target molecule has been accurately and reproducibly quantified or detected. The claimed method also fairly encompasses the detection and quantification procedures by measurement of changes in a

magnetic field, however, such measurements are to b achieved by use of a light beam. The specification is silent as to just how these methods are to be accomplished. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
>
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

3. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

5. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

6. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 30, 31, 34, 40, 41, 45, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/035822. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '822 application fairly teach or suggest the method of detection and/or quantification of a target molecule wherein a binding assay takes place of the surface of a disc, and which comprises binary data.

8. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 30-34, 40, 41, 45, 49, and 51-64 of this application conflict with claims 1-45, 48, and 50-88 of Application No. 10/035,822. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Response to argument

10. At page 10 of the response applicant's representative state "that they will defer the filing of any terminal disclaimer until the rejected claims are otherwise indicated to be in condition for allowance."

11. In view of the above remarks and in the absence of an amendment, which would remove the conflict, the rejection is maintained.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 30, 34, 40, 41, 45, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.) in view of US Patent 5,635,114 (Hong).

15. Wang et al., disclose a method of conducting assays on discs (applicant's CD or DVD), which comprise information about the assay area as well as separate regions that contain immobilized ligands.

16. Wang et al., column 4, bridging to column 7 disclose a variety of means for immobilizing various molecules. And at column 8, bridging to column 19, Wang et al., discloses various forms of the disc and how it may be configured.

17. Wang et al., column 10, bridging to column 12, disclose how the disc reader can operate, and thereby allow for the detection and/or quantification of the target analyte.

18. While Wang et al., do teach of using a disc reader to interpret the assay results, they do not each of using a device that comprises two or more reader heads.

19. Hong teach of developing CD and DVD readers that comprise multiple reader heads, and that each reader can be designed to read certain areas or regions of the disc.

20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Wang et al., with the method of Hong such that dual readers were employed such that one reader would be tasked with the collecting signals from the assay portion(s) of the disc and the other reader being tasked with the reading of information or data written on the disc as disclosed by Wang et al., and wherein the data was written in a binary manner as disclosed by Hong as such would have provided for a more fully automated capability to conducting and interpreting the data generated in the course of the assays as disclosed by Wang et al. In view of the guidance provided in the art and in the absence of convincing evidence to the contrary, claims 30, 34, 40, 41, 45, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.) in view of US Patent 5,635,114 (Hong).

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
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BLS